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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,476

Applicant(s)

FATHAUER, WILLIAM
FREDERICK

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 9 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11-12-03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 4-6, 8, 10, 11, 12, and 14-19 are objected to because of the following informalities: claims are not written in standard form. For example, in standard form Claim 4 would read:

The apparatus of Claim 3, wherein the female engagement element is of appropriate size to allow penetration...

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 3, 4, 7, 8 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claim 3, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

5. Claim 1 recites the limitation "said socket" in line 9. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 3 recites the limitation "each suture" in line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 4 and 5 recite the limitation "said straight surgical needle" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 7 recites the limitation "said perpendicular extension" in line 2. There is insufficient antecedent basis for this limitation in the claim.

9. Further, regarding Claim 7, it is not clear whether the enlarged seat is referring to the seat in Claim 1, or if a separate second seat is being claimed. Appropriate action is required.

10. Claim 8 recites the limitation "the handled framework," "said perpendicular extension," and "the arm". There is insufficient antecedent basis for this limitation in the claim.

11. Claim 18 recites the limitation "male and female engagement elements," "the straight surgical needle," "the arm," and "the suture". There is insufficient antecedent basis for this limitation in the claim.

Drawings

12. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "253" has been used to designate both a female engagement device (page 8, line 21) and a fixture (page 8, line 6-7). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to

avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

13. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "253" and "254" have both been used to designate the female engagement element. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

14. The drawings are objected to under 37 CFR 1.83(a) because they fail to show many different elements described in the specification, including, but not limited to seat 265, leading edge 266, flat proximal end 279, concave distal end 278. Any structural detail that is essential for a proper understanding of the disclosed invention should be

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shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

15. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claim 1-5, 7, 8, 10, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Shluzas, et al. (US Patent 6,051,006).

18. Shluzas'006 discloses a suturing device containing a handled framework (15) supporting opposing male (21) and female (51) engagement elements, an arm (19), a drive assembly (16) to impart motion to the male engagement element (21). The handled framework (12) further supports a perpendicular extension (50), a seat (30), and a means to position (53) a socketed fixture (59). Furthermore, the socketed fixture (50) contains means to seat and position the female engagement element (column 3, lines 7-23). The device taught by Shluzas'006 is capable of being used on bone (column 1, lines 17-22).

19. Regarding Claim 2, Shluzas'006 discloses that the male engagement element (21) is a straight surgical needle (column 4, lines 54-58).

20. Regarding Claim 3, Shluzas'006 discloses a female engagement element is cylindrical. The device is capable of being attached to two opposing ends of each suture because there are no structural differences.

21. Regarding Claim 4, Shluzas'006 discloses that the female engagement element is large enough to allow penetration by the male engagement element (21) and allow for frictional capture (Figure 7 and column 5, lines 28-32).

22. Regarding Claim 5, Shluzas'006 discloses a needle guiding device (40) which guides and supports the male engagement element (21) to its target the female engagement device (51).

23. Regarding Claim 7, Shluzas'006 discloses a handle member (12) having a forward (towards element 17) and rearward extremities. The perpendicular extension (50) extends downward from the forward extremity and terminates as an enlarged seat (30) for the socketed fixture (59).

24. Regarding Claim 8, Shluzas'006 discloses a channel (38) anterior and superior to the perpendicular extension (50), providing slidable and pivotable (34) attachment means for the arm (19) to the handle framework (12).

25. Regarding Claim 10, Shluzas'006 discloses an arm (19) supports a handle (33) at its extremity to impart slidable or pivotable motion (34) to the arm (19).

26. Regarding Claim 17, Shluzas'006 discloses that the needle (21) is a separate entity from the suture (see Figure 4).

27. Regarding Claims 18 and 19, since the device contains all of the structural requirements of the invention, it is capable of suturing the sternum. Further, the device taught by Shluzas'006 is capable of passing a suture through the sternum because Shluzas'006's device is intended for suturing device and Shluzas'006 discloses that the device can be used on bone, such as the sternum (column 2, lines 12-17).

28. Claim 1, 5, 6, and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemur (US Patent Application 2002/0013607).

29. Regarding Claim 1, Lemur'607 discloses a sternal closure device containing a handled framework (42) that supports opposing male (66) and female (bore of 21) engagement elements, an arm (64) that supports male engagement element (66), a drive assembly (62) (see paragraph [0066]) that imports motion to the male engagement element into the sternum. Further, the handled framework (42) supports a perpendicular extension (10) and a seat (13) and a means to position (43) the socked fixture (12) in the sternum. The socketed fixture can position the female engagement element because the female engagement element can slide (see element 22).

30. Regarding Claim 5, Lemur'607 discloses that the arm (64) carries the needle guiding device (element below arm 64 and above male engagement element 66 in Figure 1) straight to the female engagement element (21).

31. Regarding Claim 6, Lemur'607 discloses that the needle guiding device (element below arm 64 and above male engagement element 66 in Figure 1) contains is attached to a piston (62) which is connected to a cylinder (above arm 64), wherein the piston (62) supports a bore (hole in arm 64 that holds male engagement element 66) which stabilizes and controls male engagement element (66).

32. Regarding Claim 13, Lemur'607 discloses that the socketed fixture contains a fixed (12) and slidable member (attached to 22).

33. Regarding Claim 14, Lemur'607 discloses that the fixed and slidable members are joined by guidepins (45) and further connected by a threaded channel (20) which is

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further connected to knobbed shaft (43) providing means for the slidable member (22) to move forward or away from the fixed member (12), which alters the diameter of the socket.

34. Regarding Claim 15, Lemur'607 discloses a guidepin (45) to connect the seat (13) with fixed member (12).

35. Regarding Claim 16, Lemur'607 discloses that the socket has an upper extremity (21) and a lower extremity (12) divided by a gap that allows a suture to pass and also provides a seat (13) for the female engagement element (bore of 21).

Claim Rejections - 35 USC § 103

36. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

37. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

38. Claims 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shluzas'006, as applied to Claim 1, in further view of Hayhurst (US Patent 5,810,848).

39. Shluzas'006 teaches the limitations of Claim 9, except for the method of engaging the male and female engagement elements while in use.

40. Regarding Claim 9, Hayhurst'848 teaches a suturing system containing an arm (24) that has a series of inclined teeth (96, 98) that engage a pawl (100), which is pivotably (pin near element 102) a lever (12), which in turn is pivotably attached (108) to handled framework (80) because this allows the male engagement element to be pushed towards the female engagement element in a controlled and limited manner. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use teeth and a pawl to ensure that the male engagement element engages with the female engagement element in a controlled and limited manner.

41. Regarding Claim 11, Hayhurst'848 teaches that the lever (12) has a spring (16) for biasing the lever so that the male engagement element does not prematurely engage the female engagement element. Therefore it would have been obvious to one skilled in the art at the time the invention was made to have a spring to bias the lever in order to prevent the male engagement element from prematurely engaging with the female engagement element.

42. Regarding Claim 12, Hayhurst'848 teaches a second spring (110) for urging the pawl (100) upward to coact with inclined teeth (96, 98) in order to urge the male engagement element to engage with the female engagement element. Therefore it

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would have been obvious to one skilled in the art at the time the invention was made to use a pawl to engage with teeth, in order to force the male engagement element into contact with the female engagement element.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER**